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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,298	05/21/2001	Hidetoshi Uemura	UEMURA 6	6719

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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,298	UEMURA ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-57 and 59-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *55-57 and 59-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Amendments

Applicant's Preliminary Amendments A, B, and C, Papers Nos. 6-8 all filed with the application on May 21, 2001, have been entered, collectively amending the specification at pages 1, 22-27, 35, 36, 58-62 and 68, canceling claims 1-54 and 58, amending the claims 55-57(twice), 59(once), 64(twice), 66-69(twice), 70(once), and 71(twice) and adding claims 76-85. It is noted that Paper No. 8 indicates at page 12 that a new claim 86 would also be added, but no other claim follows claim 85 at page 32 of Paper No. 8. Consequently, claims 55-57 and 59-85 are now pending in the application.

Priority

Receipt is acknowledged of a copy in Japanese of Applicant's PCT priority document, Japanese Patent Application serial No. 10-347813 filed November 20, 1998, as well as a courtesy copy of the International Preliminary Examination Report [IPER] in Japanese, together with an English Translation of the IPER. The instant application is an English translation of the International Application PCT/JP99/06472 filed November 19, 1999. Although the seven Drawing Figures in both the International Application and PCT priority document are identical, the sequence disclosure in the International Application, where the sequence listing has 48 amino acid and nucleic acid sequences, differs from the sequence disclosure in the PCT priority document, where the sequence listing has 29 amino acid and nucleic acid sequences, suggesting that some disclosures of the International Application enjoy a priority date of only November 19, 1999, while the remainder of its disclosures enjoy a priority date of November 20, 1998. To assist in the accurate determination of priority for non-contemporaneous elements of the disclosure, Applicant is invited, but not currently required, to submit an English translation of the PCT priority document Japanese Patent Application serial No. 10-347813 filed November 20, 1998.

Election/Restrictions

Restriction is required under 35 U.S.C. §§121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a first polypeptide product having the amino acid sequence of the preproprotease set forth in the 317-amino acid sequence of SEQ ID NO:2, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the first product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the first product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 435, subclass 226.

2. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a second polypeptide product having the amino acid sequence of the preproprotease set forth in the 319-amino acid sequence of SEQ ID NO:4, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the second product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the second product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 435, subclass 226.

3. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a third polypeptide product having the amino acid sequence of the preproprotease set forth in the 306-amino acid sequence of SEQ ID NO:6, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the third product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the third product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 435, subclass 226.

4. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a fourth polypeptide product having the amino acid sequence of the peptide set forth between positions 1 through 97, inclusive, in SEQ ID NO:8, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the fourth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the fourth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

5. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a fifth polypeptide product having the amino acid sequence of the polypeptide set forth between positions 1 through 158, inclusive, in SEQ ID NO:10, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of

making the fifth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the fifth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 350.

6. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a sixth polypeptide product having the amino acid sequence of the peptide set forth between positions 1 through 82, inclusive, in SEQ ID NO:12, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the sixth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the sixth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

7. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a seventh polypeptide product having the amino acid sequence of the polypeptide set forth between positions 1 through 185, inclusive, in SEQ ID NO:14, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the seventh product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the seventh product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 350.

8. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to an eighth polypeptide product having the amino acid sequence of the peptide set forth between positions 1 through 80, inclusive, in SEQ ID NO:16, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the eighth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the eighth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

9. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a ninth polypeptide product having the amino acid sequence of the polypeptide set forth between positions 1 through 253, inclusive, in SEQ ID NO:18, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the ninth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the ninth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 350.

10. Claims 76-79, 55-57, 57, 59, 82 and 83, drawn, in part, to a tenth polypeptide product having the amino acid sequence of the preproprotease set forth in the 308-amino acid sequence of SEQ ID NO:20, or proprotease or mature protease fragments thereof or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the tenth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the tenth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 435, subclass 226.

11. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to an eleventh polypeptide product having the 34-amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:2, or variants or modified

derivatives thereof, and to a composition comprising same, to a first method of making the eleventh product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the eleventh product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

12. Claims 76, 77, 55-57, 59, 82 and 83, drawn, in part, to a twelfth polypeptide product having the 15-amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:2, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the twelfth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the twelfth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

13. Claims 76-79, 55, 56, 82 and 83, drawn, in part, to a thirteenth polypeptide product having the 34-amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the thirteenth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the thirteenth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

14. Claims 76-79, 55, 56, 82 and 83, drawn, in part, to a fourteenth polypeptide product having the 15-amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, and to a composition comprising same, to a first method of making the fourteenth product utilizing an encoding polynucleotide, as well as vectors and host cells comprising the polynucleotide, and to a first method of use of the fourteenth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 530, subclass 300.

15. Claims 64-70, 80 and 81, drawn, in part, to a fifteenth product, an antibody specific for a polypeptide having the amino acid sequence of the preproprotease set forth in the 317-amino acid sequence of SEQ ID NO:2, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the preproprotease set forth within the 317-amino acid sequence of SEQ ID NO:2, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

16. Claims 64-70, 80 and 81, drawn, in part, to a sixteenth product, an antibody specific for a polypeptide having the amino acid sequence of the preproprotease set forth in the 319-amino acid sequence of SEQ ID NO:4, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the preproprotease set forth within the 319-amino acid sequence of SEQ ID NO:4, or proprotease or mature protease fragments thereof or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

17. Claims 64-70, 80 and 81, drawn, in part, to a seventeenth product, an antibody specific for a polypeptide having the amino acid sequence of the preproprotease set forth in the 306-amino acid sequence of SEQ ID NO:6, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the preproprotease set forth in the 306-amino acid sequence of SEQ ID NO:6, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

18. Claims 64-70, 80 and 81, drawn, in part, to a eighteenth product, an antibody specific for a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 97, inclusive, in SEQ ID NO:8, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 97, inclusive, in SEQ ID NO:8, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

19. Claims 64-70, 80 and 81, drawn, in part, to a nineteenth product, an antibody specific for a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 158, inclusive, in SEQ ID NO:10, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 158, inclusive, in SEQ ID NO:10, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

20. Claims 64-70, 80 and 81, drawn, in part, to a twentieth product, an antibody specific for a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 82, inclusive, in SEQ ID NO:12, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 82, inclusive, in SEQ ID NO:12, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

21. Claims 64-70, 80 and 81, drawn, in part, to a twenty-first product, an antibody specific for a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 185, inclusive, in SEQ ID NO:14, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 185, inclusive, in SEQ ID NO:14, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

22. Claims 64-70, 80 and 81, drawn, in part, to a twenty-second product, an antibody specific for a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 80, inclusive, in SEQ ID NO:16, or

variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide set forth between positions 1 through 80, inclusive, in SEQ ID NO:16, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

23. Claims 64-70, 80 and 81, drawn, in part, to a twenty-third product, an antibody specific for a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 253, inclusive, in SEQ ID NO:18, or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the polypeptide set forth between positions 1 through 253, inclusive, in SEQ ID NO:18, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

24. Claims 64-70, 80 and 81, drawn, in part, to a twenty-fourth product, an antibody specific for a polypeptide having the amino acid sequence of the preproprotease set forth in the 308-amino acid sequence of SEQ ID NO:20, or proprotease or mature protease fragments thereof or variants or modified derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the preproprotease set forth in the 308-amino acid sequence of SEQ ID NO:20, or proprotease or mature protease fragments thereof or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

25. Claims 64-70, 80 and 81, drawn, in part, to a twenty-fifth product, an antibody specific for a polypeptide having the amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:2, or variants or derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:2, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

26. Claims 64-70, 80 and 81, drawn, in part, to a twenty-sixth product, an antibody specific for a polypeptide having the amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:2, or variants or derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:2, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

27. Claims 64-70, 80 and 81, drawn, in part, to a twenty-seventh product, an antibody specific for a polypeptide having the amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:20, or variants or derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

28. Claims 64-70, 80 and 81, drawn, in part, to a twenty-eighth product, an antibody specific for a polypeptide having the amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:20, or variants or derivatives thereof, which antibody may be an monoclonal, antibody, and to a first method of making the fifteenth product comprising vaccinating an animal with a polypeptide having the amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, classified under national practice in, *inter alia*, class 530, subclass 387.1.

29. Claims 60-62, drawn to a twenty-ninth product, a non-human transgenic animal wherein the expression of any one of ten species of BSSP4 genes has been altered, classified under national practice in class 800, subclass 8.

30. Claim 63, drawn to a thirtieth product, a knockout mouse wherein the expression of any one of ten species of BSSP4 genes is deficient, classified under national practice in class 800, subclass 18.

31. Claims 71-75, 84 and 85, drawn, in part, to a thirty-first product, an unspecified diagnostic marker compound comprising an amino acid sequence of the preproprotease set forth in the 317-amino acid sequence of SEQ ID NO:2, or proprotease or mature protease fragments thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 424, subclass 94.1.

32. Claims 71-75, 84 and 85, drawn, in part, to a thirty-second product, an unspecified diagnostic marker compound comprising an amino acid sequence of the preproprotease set forth in the 319-amino acid sequence of SEQ ID NO:4, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 424, subclass 94.1.

33. Claims 71-75, 84 and 85, drawn, in part, to a thirty-third product, an unspecified diagnostic marker compound comprising an amino acid sequence of the preproprotease set forth in the 306-amino acid sequence of SEQ ID NO:6, or proprotease or mature protease fragments thereof, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 424, subclass 94.1.

34. Claims 71-75, 84 and 85, drawn, in part, to a thirty-fourth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide set forth between positions 1 through 97, inclusive, in SEQ ID NO:8, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

35. Claims 71-75, 84 and 85, drawn, in part, to a thirty-fifth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the polypeptide set forth between positions 1 through 158, inclusive, in SEQ ID NO:10, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

36. Claims 71-75, 84 and 85, drawn, in part, to a thirty-sixth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide set forth between positions 1 through 82, inclusive, in SEQ ID NO:12, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

37. Claims 71-75, 84 and 85, drawn, in part, to a thirty-seventh product, an unspecified diagnostic marker compound comprising an amino acid sequence of the polypeptide set forth between positions 1 through 185, inclusive, in SEQ ID NO:14, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

38. Claims 71-75, 84 and 85, drawn, in part, to a thirty-eighth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide set forth between positions 1 through 80, inclusive, in SEQ ID NO:16, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

39. Claims 71-75, 84 and 85, drawn, in part, to a thirty-ninth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the polypeptide set forth between positions 1 through 253, inclusive, in SEQ ID NO:18, or variants or modified derivatives thereof, and to a method of detection thereof, of the ninth product in an assay to detect an inhibitor of serine protease activity, classified under national practice in, *inter alia*, class 514, subclass 1.

40. Claims 71-75, 84 and 85, drawn, in part, to a fortieth polypeptide product, an unspecified diagnostic marker compound comprising an amino acid sequence of the preproprotease set forth in the 308-amino acid sequence of SEQ ID NO:20, or proprotease or mature protease fragments thereof or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 424, subclass 94.1.

41. Claims 71-75, 84 and 85, drawn, in part, to an forty-first product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:2, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

42. Claims 71-75, 84 and 85, drawn, in part, to a forty-second product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:2, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

43. Claims 71-75, 84 and 85, drawn, in part, to a forty-third product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide between positions −49 and −16, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

44. Claims 71-75, 84 and 85, drawn, in part, to a forty-fourth product, an unspecified diagnostic marker compound comprising an amino acid sequence of the peptide between positions −15 and −1, inclusive, of SEQ ID NO:20, or variants or modified derivatives thereof, and to a method of detection thereof, classified under national practice in, *inter alia*, class 514, subclass 1.

This application contains claims 60-63 directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a preproprotease set forth in the 317-amino acid sequence of SEQ ID NO:2,

(ii) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a preproprotease set forth in the 319-amino acid sequence of SEQ ID NO:4,

(iii) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a preproprotease set forth in the 306-amino acid sequence of SEQ ID NO:6,

(iv) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a peptide set forth between positions 1 through 97, inclusive, in SEQ ID NO:8,

(v) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a polypeptide set forth between positions 1 through 158, inclusive, in SEQ ID NO:10,

(vi) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a peptide set forth between positions 1 through 82, inclusive, in SEQ ID NO:12,

(vii) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a polypeptide set forth between positions 1 through 185, inclusive, in SEQ ID NO:14,

(viii) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a peptide set forth between positions 1 through 80, inclusive, in SEQ ID NO:16,

(ix) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a polypeptide set forth between positions 1 through 253, inclusive, in SEQ ID NO:18, and,

(x) a transgenic animal having an altered expression of, or a deficient function of, a gene specifying a preproprotease set forth in the 308-amino acid sequence of SEQ ID NO:20.

Applicant is required, in reply to this action and with the election of either of Group 29 or 30 above, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37

CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims 60-63 are deemed to correspond to the species listed above in the following manner: Each of claims 60-63 is considered to refer to a BSSP4 gene disclosed in the specification, of which 10 structurally distinct species are identified by their specific coding capacities permitting an identification as claimed subject matter. The following claim(s) are generic: 60-63. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The structure of the separate genes, as demonstrated by their differing coding capacities are distinct, each from another, and are not disclosed to have any special technical feature with which their cellular functions can be shown to be shared, thus a transgenic animal having an altered expression, or a deficient expression, of one BSSP4 gene cannot be considered to share any special technical feature with a transgenic animal having an altered expression, or a deficient expression, of a different BSSP4 gene.

The inventions listed as Groups 1-44 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups 1-14 lack unity of invention, each with the other, because the claims common to each Group describe as many as fourteen separate and distinct peptide or polypeptide products, each is disclosed to have a special technical feature defined by its primary structure of a native peptide, protein, or domain, which need not comprise the amino acid sequence of any other disclosed, mature, polypeptide or peptide that might be considered to link any one of them to another the absence of disclosure of a further special technical feature common to any of the fourteen native peptide or polypeptide products.

Inventions of Groups 1-14 lack unity of invention with inventions of Groups 15-28 because the peptide and polypeptide products of Group 1-14 are unrelated in structure and function to antibody products of Groups 15-28 and are not disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 1-14 lack unity of invention with inventions of Groups 29 and 30 because the peptide and polypeptide products of Group 1-14 are unrelated in structure and function to transgenic animals and knockout mice of Groups 29 and 30 and are not disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 1-14 lack unity of invention with inventions of Groups 31-44 because the peptide and polypeptide products of Group 1-14 are not disclosed to be related in structure and function to diagnostic markers of Groups 31-44, nor are they disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 15-28 lack unity of invention, each with the other, because the claims common to each Group describe as many as fourteen separate and distinct antibodies, where each is required to have a special technical feature defined by its ability to bind specifically to the primary structure of a native peptide, protein, or domain, which need not comprise the amino acid sequence of any other disclosed, mature, polypeptide or peptide and because the basis for recognition differs and because none is disclosed to be capable of recognizing a product recognized by another, no two of the antibody products can be considered to share a special technical feature.

Inventions of Groups 15-28 lack unity of invention with inventions of Groups 29 and 30 because the antibody products of Group 15-28 are unrelated in structure and function to transgenic animals and knockout mice of Groups 29 and 30 and are not disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 15-28 lack unity of invention with inventions of Groups 31-44 because the antibody products of Group 15-28 are not disclosed to be related in structure and function to diagnostic markers of Groups 31-44, nor are they disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 29 and 30 lack unity of invention because the transgenic animals of Group 29 are not required, as claimed, to have the deficient expression of a gene as required by Group 30, nor are they disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Group 29 lack unity of invention with inventions of Groups 31-44 because the transgenic animals of Group 29 are not required, to have express a diagnostic marker of Group 31-44, nor are they disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 30 lack unity of invention with inventions of Groups 31-44 because the transgenic animals of Group 30 are not required, to have the deficient expression of a diagnostic marker of Groups 31-44, nor are they disclosed to capable of concurrent use, thus share no special technical feature.

Inventions of Groups 31-44 lack unity of invention, each with the other, because the claims common to each Group describe as many as fourteen separate and distinct diagnostic markers where, although no specific structure is disclosed for any, each is required to mark the presence or absence of a separate and distinct peptide or polypeptide product, thus has a special technical feature defined by its ability to mark a native peptide, protein, or domain, which capability is not disclosed to be shared among several, or any pair of, disclosed native peptide, protein, or domain, thus none cannot be considered to share any special technical feature with another.

Because these inventions lack unity and are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

A telephone call was made to Mr. Allen C. Yun on June 18, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
June 18, 2003